

REMARKS/ARGUMENTS

Claims 13-18, 21-32 and 40 are active. Claim 13 has been revised to remove the functional limitations inherent in N-deoxyribosyltransferase and corrected as suggested by the Examiner. Claim 16 has been revised to distinguish it from claim 15, support is found on page 8, line 7 of the specification. Claim 17 has been clarified. No new matter has been introduced. The proposed amendments do not raise new issues or necessitate a new search by the Examiner, since the amendments are editorial or corrective in nature. Therefore, the Applicants respectfully request that this after-final Amendment be entered to place this application in condition for allowance or to simplify the issues for appeal.

Interview Summary

On April 8, 2010, the Applicants' representative discussed this case with Examiner Joike. The Applicants proposed amendments to avoid the objection and indefiniteness rejections which were indicated as generally acceptable by the Examiner. The description rejection was reviewed and the Applicants pointed out express support for the limitations in the present claims. With regard to enablement, the Applicants believe that the Examiner agreed that the specification taught how to make the invention, however, to avoid a possible enablement rejection, the Examiner requested that the Applicants further explain how one of skill in the art would know "how to use" the invention, especially for claims containing terms such as "at least 90% identity".

Allowable Subject Matter

The Applicants thank Examiner Joike for indicating that claim 40 is allowable.

Restriction/Election

The Applicants previously elected with traverse **Group II**, claims 13-32 and 40, directed to DTP protein, nucleic acid, vectors and host cells. The requirement has been made FINAL. The Applicants respectfully request that the claims of the nonelected group(s) or other withdrawn subject matter which depend from or otherwise include all the limitations of an allowed elected claim, be rejoined upon an indication of allowability for the elected claim, see MPEP 821.04.

Rejection—35 U.S.C. §112, second paragraph

Claim 17 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite. This rejection is moot in view of the amendments above.

Rejection—35 U.S.C. §112, first paragraph

Claims 13-16, 21-26, and 28-32 were rejected under 35 U.S.C. 112, first paragraph, as lacking adequate written description. Independent claim 13 has been revised to remove the functional limitation and structurally describes a genus of proteins disclosed by original claims 15 and 16 (which recite sequence identity limitations) and on pages 7-8 of the specification. These portions of the original disclosure expressly disclose the claimed genus of protein sequences and establish that the Applicants were in possession of this subject matter at the time of invention. Accordingly, this rejection cannot be sustained.

Enablement

Upon entry of this amendment, independent claim 13 would read as follows:

Claim 13 (Currently Amended): A protein that has at least 90% identity with the polypeptide of SEQ ID NO: 2 or SEQ ID NO: 4, but which is not SEQ ID NO: 2;

that retains residues Y13, D77, D97, E103, and M132 that respectively correspond to positions 13, 77, 97, 103, and 132 of SEQ ID NO: 2; and
that has threonine at a position corresponding to position 15 of SEQ ID NO: 2 or SEQ ID NO: 4.

How to Make. As discussed in the recent interview, those of skill in the art would have been able to make the claimed protein without undue experimentation since biological and synthetic methods for making particular polypeptide sequences were well-known and because the specification precisely describes the structural features of the claimed genus of proteins, i.e., they are at least 90% identical to SEQ ID NO: 2 or 4 and have particular amino acids at particular defined positions. As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement required of 35 U.S.C. 112, first paragraph is satisfied, MPEP 2164.01(b): *How to Make the Claimed Invention*. Page 1, lines 16-18 describe chemical synthesis of proteins such as N-deoxyribosyl transferases of *Lactobacillus fermentum*; and page 1, line 30-page 9 of the specification describe methods of making variant proteins by mutagenesis and subsequent biological or recombinant expression.

How to Use. Those of skill in the art, guided by the present disclosure, would have been able to use the claimed polypeptides without undue experimentation. Even a considerable amount of experimentation is permissible, if it is merely routine, or if the specification provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed, *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988). Furthermore, the presence of inoperative embodiments within the scope of a claim does not necessarily render a claim nonenabled. The standard is whether a skilled person could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with expenditure of no more effort than is normally required in the art. *Atlas*

Powder Co. v. E.I. duPont de Nemours & Co., 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984).

The present claims cover a subgenus of proteins significantly narrower than a subgenus of proteins having “at least 90% identity” to SEQ ID NOS: 2 and 4, because the claims require particular amino acid substitutions at particular residues. These particular substitutions have been found to correlate with enzymatic activity, thus providing a nexus between structure and function, see the bottom of page 7 of the specification. Even were this nexus absent, no undue experimentation would have been required to identify enzymatically active members of the claimed subgenus for the following reasons enumerated following the *Wands* factors:

(A) the breadth of the present claims limits the claimed proteins to those which have at least 90% sequence identity with SEQ ID NO: 2 or SEQ ID NO: 4 **and** which have particular amino acid residues at the positions corresponding to residues 13, 15, 77, 97, 103, and 132 of SEQ ID NO: 2 or 4.

(B) The nature of the invention with regard to “how to use” involves catalytic activities on known substrates and thus use of the claimed proteins is straightforward and well within the skill of the art.

(C) The state of the prior art shows that methods for using transferases were well-known and sections 3.2 - 5 of the present specification disclose how to screen proteins for such enzymatic activity.

(D) The level of ordinary skill in the molecular biological arts is high, generally Ph.D or post-doctoral level.

(E) The level of predictability in the art is high, since the sequences of SEQ ID NOS: 2 and 4 are fully disclosed and methods for making and screening variants of these sequences are disclosed in the specification or well-known in the art.

(F) and (G) The amount of direction provided by the present inventors is high and the claimed method is exemplified in sections 3.2 - 6 of the specification.

(H) The quantity of experimentation needed to use the invention is limited to identifying members of the claimed subgenus having useful activities, such as transferase activity.

Consequently, those of skill in the art at the time of invention would have been able to both make and use the claimed subgenus of proteins without undue experimentation and there is no basis for an enablement rejection.

Conclusion

In view of the amendments and remarks above, the Applicants respectfully submit that this application is now in condition for allowance. An early notice to that effect is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.
Norman F. Oblon

A handwritten signature in black ink, appearing to read "Thomas M. Cunningham", is written over a horizontal line.

Thomas M. Cunningham, Ph.D.
Registration No. 45,394

Customer Number
22850

Tel: (703) 413-3000
Fax: (703) 413 -2220
(OSMMN 08/07)